

MEDICAL POLICY – 8.01.532

Hematopoietic Cell Transplantation in the Treatment of Germ-Cell Tumors


BCBSA Ref. Policy: 8.01.35

Effective Date: Apr. 1, 2026
 Last Revised: Mar. 23, 2026
 Replaces: 8.01.35

RELATED MEDICAL POLICIES:	
8.01.15	Hematopoietic Cell Transplantation for Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma
8.01.24	Hematopoietic Cell Transplantation for Miscellaneous Solid Tumors in Adults
8.01.25	Hematopoietic Cell Transplantation for Autoimmune Diseases
8.01.29	Hematopoietic Cell Transplantation for Hodgkin Lymphoma
8.01.511	Hematopoietic Cell Transplantation for Solid Tumors of Childhood
8.01.529	Hematopoietic Cell Transplantation for Non-Hodgkin Lymphomas
8.01.539	Allogeneic Hematopoietic Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms

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Introduction

Germ cells are cells in a woman’s ovaries and a man’s testicles that can develop into eggs or sperm. Tumors can sometimes start in the germ cells. Most of the time, germ cell tumors grow in a woman’s ovaries or a man’s testicles, but rarely germ cells can move to other parts of the body and grow into tumors in those locations. Surgery, chemotherapy and radiation are often used to treat germ cell tumors. Sometimes, treatment may include a stem cell transplant using the patient’s own cells. Stem cells are collected from the patient’s blood and stored. After the patient receives high-dose chemotherapy, stem cells are given back to the patient. Using a person’s own stem cells is known as an autologous stem cell transplant. Using stem cells from a donor is called an allogeneic transplant. Using donor stem cells to treat germ cell tumors is investigational (unproven) because there is not enough scientific evidence to show that it works for this condition.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for

providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Medical Necessity
Single autologous HCT	<p>Single autologous hematopoietic cell transplantation (HCT) may be considered medically necessary as salvage therapy for germ-cell tumors:</p> <ul style="list-style-type: none"> In individuals with favorable prognostic factors that have failed a previous course of conventional-dose salvage chemotherapy <p>OR</p> <ul style="list-style-type: none"> In individuals with unfavorable prognostic factors as initial treatment of first relapse (i.e., without a course of conventional-dose salvage chemotherapy) and in individuals with platinum-refractory disease (see Favorable and Unfavorable Prognostic Factors below).
Tandem or sequential autologous HCT	<p>Tandem or sequential autologous HCT may be considered medically necessary for the treatment of testicular tumors either as salvage therapy or with platinum-refractory disease.</p>

Service	Investigational
Autologous HCT	<p>Autologous hematopoietic cell transplantation (HCT) is considered investigational as a component of first-line treatment for germ-cell tumors.</p>
Allogeneic HCT	<p>Allogeneic HCT is considered investigational to treat germ-cell tumors, including, but not limited to use as therapy after a prior failed autologous HCT.</p>

Favorable and Unfavorable Prognostic Factors

The favorable and unfavorable prognostic factors listed next are derived from the current National Comprehensive Cancer Network (NCCN) guidelines and DeVita et al's textbook *Cancer: Principles and Practice of Oncology* (2015, pp. 988-1004).



Favorable and Unfavorable Prognostic Factors

Individuals with favorable prognostic factors include those with a testis or retroperitoneal primary site, a complete response to initial chemotherapy, low levels of serum markers, and low volume disease. Individuals with unfavorable prognostic factors are those with an extra testicular primary site, an incomplete response to initial therapy, high levels of serum markers, high-volume disease, or relapsing mediastinal nonseminomatous germ cell tumors.

Documentation Requirements

The individual's medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of:

- Diagnosis/condition
- History and physical examination documenting the severity of the condition
- Prior treatment individual has received
- Favorable and unfavorable prognostic factors

Coding

Code	Description
CPT	
38230	Bone marrow harvesting for transplantation; allogeneic
38232	Bone marrow harvesting for transplantation; autologous
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
38241	Hematopoietic progenitor cell (HPC); autologous transplantation
HCPCS	
S2142	Cord blood derived stem cell transplantation, allogeneic
S2150	Bone marrow or blood-derived stem cells (peripheral or umbilical), allogeneic or autologous, harvesting, transplantation, and related complications including phoresis and cell preparation/storage; marrow ablative therapy; drugs, supplies, hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre- and posttransplant care in the global definition

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).



Related Information

Benefit Application

The following considerations may supersede this policy:

- State mandates requiring coverage for autologous bone marrow transplantation offered as part of National Institutes of Health–approved clinical trials of autologous bone marrow transplantation.
- Some plans may participate in voluntary programs offering coverage for individuals participating in National Institutes of Health–approved clinical trials of cancer chemotherapies, including autologous bone marrow transplantation.
- Some contracts or certificates of coverage may include specific conditions in which autologous bone marrow transplantation would be considered eligible for coverage.

Evidence Review

Description

Therapy for germ cell tumors is generally dictated by several factors, including disease stage, tumor histology, primary site of tumor, and response to chemotherapy. Individuals with unfavorable prognostic factors may be candidates for hematopoietic cell transplantation (HCT).

Background

Germ-Cell Tumors

Germ-cell tumors are composed primarily of testicular neoplasms as well as ovarian and extragonadal germ-cell tumors (no primary tumor in either testis or ovary). Germ-cell tumors are classified by their histology, stage, prognosis, and response to chemotherapy.



The most common testicular germ cell tumors are seminomas; all other histologic types are collectively referred to as nonseminomatous tumors.¹ Nonseminomatous tumor types include embryonal cell tumor, yolk sac tumor, and teratomas. Malignant germ cell tumors of ovarian origin are classified as dysgerminomas or nondysgerminomas.² Similarly, nondysgerminomas include immature teratomas, embryonal cell tumors, yolk sac tumor, polyembryoma, and mixed germ cell tumors.

Staging

Stage depends on location and extent of the tumor, using the American Joint Committee on Cancer's TNM system. TNM stages, modified by serum concentrations of markers for tumor burden (S0-3) when available, are grouped by similar prognoses. Markers used for germ cell tumors include human β -chorionic gonadotropin, lactate dehydrogenase, and α -fetoprotein. However, most individuals with pure seminoma have normal α -fetoprotein concentrations. For testicular tumors, stages IA-B tumors are limited to the testis (no involved nodes or distant metastases) and no marker elevations (S0); Stages IIA-C have increasing size and number of tumor-involved lymph nodes, and at least one marker moderately elevated above the normal range (S1), and Stages IIIA-C have distant metastases and/or marker elevations greater than specified thresholds (S2-3).

Germ cell tumors also are divided into good-, intermediate-, or poor-risk categories based on histology, site, extent of primary tumor, and serum marker levels. Good-risk pure seminomas can be at any primary site, do not have extra-pulmonary visceral metastases or marker elevations. Intermediate-risk pure seminomas have extra-pulmonary visceral metastases with or without elevated human chorionic gonadotropin and/or lactate dehydrogenase. There are no poor-risk pure seminomas, but mixed histology tumors and seminomas with elevated α -fetoprotein (due to mixture with non-seminomatous components) are managed as non-seminomatous germ-cell tumors. Good- and intermediate-risk non-seminomatous germ-cell tumors have testicular or retroperitoneal tumors without extra-pulmonary visceral metastases, and either S1 (good risk) or S2 (intermediate) levels of marker elevations. Poor-risk tumors have mediastinal primary tumors, or extra-pulmonary visceral metastases, or the highest level (S3) of marker elevations.

Hematopoietic Cell Transplantation

HCT is a procedure in which hematopoietic stem cells are intravenously infused to restore bone marrow function in cancer patients who receive bone marrow-toxic doses of cytotoxic drugs



with or without whole body radiotherapy. Hematopoietic stem cells may be obtained from the transplant recipient (autologous HCT) or from a donor (allogeneic HCT [allo-HCT]). They can be harvested from bone marrow, peripheral blood, or umbilical cord blood shortly after delivery of neonates.

Immunologic compatibility between infused hematopoietic stem cells and the recipient is not an issue in autologous HCT. In allogeneic stem cell transplantation, immunologic compatibility between donor and patient is a critical factor for achieving a successful outcome. Compatibility is established by typing of human leukocyte antigens (HLA) using cellular, serologic, or molecular techniques. HLA refers to the gene complex expressed at the HLA-A, -B, and -DR (antigen-D related) loci on each arm of chromosome 6. An acceptable donor will match the patient at all or most of the HLA loci.

Conditioning for Hematopoietic Cell Transplantation

Conventional Conditioning

The conventional (“classical”) practice of allo-HCT involves administration of cytotoxic agents (e.g., cyclophosphamide, busulfan) with or without total body irradiation at doses sufficient to cause bone marrow ablation in the recipient. The beneficial treatment effect of this procedure is due to a combination of the initial eradication of malignant cells and subsequent graft-versus-malignancy effect mediated by non-self-immunologic effector cells. While the slower graft-versus-malignancy effect is considered the potentially curative component, it may be overwhelmed by existing disease in the absence of pretransplant conditioning. Intense conditioning regimens are limited to individuals who are sufficiently medically fit to tolerate substantial adverse effects. These include opportunistic infections secondary to loss of endogenous bone marrow function and organ damage or failure caused by cytotoxic drugs. Subsequent to graft infusion in allo-HCT, immunosuppressant drugs are required to minimize graft rejection and graft-versus-host disease (GVHD), which increases susceptibility to opportunistic infections.

The success of autologous HCT is predicated on the potential of cytotoxic chemotherapy, with or without radiotherapy, to eradicate cancerous cells from the blood and bone marrow. This permits subsequent engraftment and repopulation of the bone marrow with presumably normal hematopoietic stem cells obtained from the individual before undergoing bone marrow ablation. Therefore, autologous HCT is typically performed as consolidation therapy when the individual’s disease is in complete remission. Individuals who undergo autologous HCT are also



susceptible to chemotherapy-related toxicities and opportunistic infections before engraftment, but not GVHD.

Reduced Intensity Conditioning Allogeneic Hematopoietic Cell Transplantation

Reduced intensity conditioning (RIC) refers to the pretransplant use of lower doses of cytotoxic drugs or less intense regimens of radiotherapy than are used in traditional full-dose myeloablative conditioning treatments. Although the definition of RIC is variable, with numerous versions employed, all regimens seek to balance the competing effects of relapse due to residual disease and non-relapse mortality. The goal of RIC is to reduce disease burden and to minimize associated treatment-related morbidity and non-relapse mortality in the period during which the beneficial graft-versus-malignancy effect of allogeneic transplantation develops. RIC regimens range from nearly total myeloablative to minimally myeloablative with lymphoablation, with intensity tailored to specific diseases and patient condition. Individuals who undergo RIC with allo-HCT initially demonstrate donor cell engraftment and bone marrow mixed chimerism. Most will subsequently convert to full-donor chimerism. In this review, the term reduced-intensity conditioning will refer to all conditioning regimens intended to be nonmyeloablative.

Summary of Evidence

For individuals who have previously untreated germ cell tumors who receive autologous HCT as first-line therapy, the evidence includes randomized controlled trials (RCTs). The relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. Results from the RCTs have shown that autologous HCT as initial therapy for germ cell tumors did not significantly improve outcomes compared with alternative therapy (e.g., standard-dose chemotherapy). Study sample sizes were relatively small and may have been underpowered to detect differences between groups. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have relapsed or have refractory germ cell tumors who receive autologous HCT, the evidence includes an RCT and several case series. The relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. The single published RCT did not find improved outcomes with high-dose chemotherapy (HDC) and autologous HCT compared with standard-dose HCT. Case series had a wide range of sample sizes. Progression-free and overall survival rates varied by prior treatment experience, prognostic factors, number of high-dose chemotherapy and autologous stem cell transplantation cycles



and whether additional consolidation treatment such as radiation therapy was included. However, two- and three-year progression-free survival rates of 50-60% have consistently been achieved. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have germ cell tumors who receive tandem autologous transplantation and sequential high-dose chemotherapy (HDC), the evidence includes an RCT, several retrospective cohort studies, and a comparative effectiveness review. The relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. The RCT reported a higher rate of treatment-related mortality with sequential HDC compared with single HDC. However, 5-year survival outcomes did not differ significantly between groups. Overall, the available studies have included heterogeneous patient populations, in different salvage treatment settings (i.e., first vs subsequent salvage therapy), and have lacked a universally accepted prognostic scoring system to risk-stratify patients. Tandem autologous transplant or transplant with sequential HDC has not shown benefit in individuals with primary mediastinal germ cell tumors. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have germ cell tumors who receive allogeneic HCT, the evidence includes a case report. The relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. There were no RCTs or nonrandomized comparative studies evaluating allogeneic HCT for germ cell tumors. One 2007 case report has described successful treatment of a refractory mediastinal gem cell tumor with allogeneic HCT. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in [Table 1](#).

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			



NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT02375204	A Randomized Phase III Trial Comparing Conventional-Dose Chemotherapy Using Paclitaxel, Ifosfamide, and Cisplatin (TIP) With High-Dose Chemotherapy Using Mobilizing Paclitaxel Plus Ifosfamide Followed by High-Dose Carboplatin and Etoposide (TI-CE) as First Salvage Treatment in Relapsed or Refractory Germ Cell Tumors	420	Jun 2031
Unpublished			
NCT00432094	Autologous Peripheral Blood Stem Cell Transplant for Germ-Cell Tumors	23	Mar 2021

NCT: National clinical trial

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2010 Input

In response to requests, input was received from three physician specialty societies, three academic medical centers, and five Blue Distinction Centers for Transplants while this policy was under review in 2010. There was general agreement with the policy statements regarding the use of single autologous HCT as salvage therapy, the use of autologous HCT as first-line treatment, and the use of allogeneic HCT. Seven reviewers felt that tandem autologous transplant or transplant with sequential HCT is medically necessary for individuals as salvage therapy or with platinum-refractory disease; two reviewers felt that tandem transplant or sequential high-dose chemotherapy was investigational.



Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Comprehensive Cancer Network

Current National Comprehensive Cancer Network (NCCN) guidelines on ovarian cancer (v3.2025) state that high-dose chemotherapy with hematopoietic cell transplant is among preferred regimens as potentially curative therapy for recurrent malignant germ cell tumors.²⁴

Current NCCN guidelines on testicular cancer (v1.2026) state that, second-line chemotherapy regimens for metastatic germ cell tumors include high-dose chemotherapy with stem cell support.²⁴

American Society for Transplantation and Cellular Therapy

In 2020, the guidelines by the American Society for Transplantation and Cellular Therapy were published on indications for autologous and allogeneic HCT.²⁵ Recommendations were intended to describe the current consensus on use of HCT within and outside of the clinical trial setting. Recommendations on germ cell tumors are listed in [Table 2](#).

Table 2. Recommendations on Allogeneic and Autologous HCT

Indications	Allogeneic HCT	Autologous HCT
Pediatric		
Germ cell tumor, relapse	D	C
Germ cell tumor, refractory	D	C
Adult		



Indications	Allogeneic HCT	Autologous HCT
Germ cell tumor, relapse	N	S
Germ cell tumor, refractory	N	S

C: clinical evidence available, standard of care; D: developmental (i.e., promising); HCT: hematopoietic cell transplantation; N: not generally recommended; S: standard of care.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

The US Food and Drug Administration regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation, title 21, parts 1270 and 1271. Hematopoietic stem cells are included in these regulations.

References

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History

Date	Comments
06/09/14	New PR policy replacing 8.01.35, added to Therapy section. Policy developed with literature review through March 5, 2014. Policy statement on tandem or sequential autologous HSCT as medically necessary for the treatment of testicular tumors germ cell tumors either as salvage therapy or with platinum-refractory disease now requires enrollment in a clinical trial.
02/03/15	Update Related Policies. Remove 8.01.23, 8.01.28 and 8.01.30.
06/09/15	Annual Review. Policy updated with literature review; no change in policy statements. ICD-9 and ICD-10 diagnosis and procedure codes removed; these were for informational purposes only.
09/01/16	Update Related Policies. Remove 8.01.27 as it was archived.
11/01/16	Annual Review, approved October 11, 2016. Policy updated with literature review through June 14, 2016; references 2, 17, 38, and 46 added. Policy statements unchanged. Removed codes that are transplant benefit related. Codes listed in the policy will be reviewed for medical necessity.
04/01/17	Annual Review, approved March 14, 2017. Policy updated with literature review through November 9, 2016; references 9 and 20 added. Changed "hematopoietic stem cell transplantation" to "hematopoietic cell transplantation" per NCCN terminology change. Policy statements unchanged.
06/09/17	Coding update; updated description for CPT codes 38230, 38240, and 38241.
08/01/17	Updated title of Related Policy 8.01.511.
12/01/17	Policy moved into new format; no change to policy statements.
06/01/18	Annual Review, approved May 3, 2018. Policy statements unchanged.
05/01/19	Annual Review, approved April 18, 2019. Policy updated with literature review through December 2018; references 6-7 added, reference 21 updated. Policy statements unchanged.
04/01/20	Coding update. Removed CPT code 38242, does not match criteria.



Date	Comments
05/01/20	Annual Review, approved April 23, 2020. Policy updated with literature review through November 2019; reference on NCCN guidelines updated. Policy statements unchanged.
05/06/20	Delete policy, approved May 5, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
06/10/20	Interim Review, approved June 9, 2020, effective June 10, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.
04/01/21	Annual Review, approved March 23, 2021. Policy updated with literature review through December 3, 2020; reference on NCCN guidelines updated. Policy statements unchanged. Update Related Policies, removed reference to 8.01.22 and replaced with 8.01.538.
04/01/22	Annual Review, approved March 21, 2022. Policy updated with literature review through November 18, 2021; references added; NCCN guidelines and American Society for Transplantation and Cellular Therapy guideline updated; Policy statements unchanged.
10/01/22	Coding update. Removed HCPC code S2140.
04/01/23	Annual Review, approved March 20, 2023. Policy updated with literature review through December 1, 2022; no references added; NCCN guidelines updated. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
04/01/24	Annual Review, approved March 25, 2024. Policy updated with literature review through November 30, 2023; references added. Policy statements unchanged. Updated Related Policy section; 8.01.21 was replaced by 8.01.539 Allogeneic Hematopoietic Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms.
10/09/24	Minor update. Removed policy 8.01.538 Allogeneic Hematopoietic Cell Transplantation for Genetic Diseases and Acquired Anemias from the Related Policy section.
04/01/25	Annual Review, approved March 10, 2025. Policy updated with literature review through November 22, 2024; references added. Policy statements unchanged.
04/01/26	Annual Review, approved March 23, 2026. Policy updated with literature review through December 9, 2025; no references added. Policy statements unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.



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Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

